N,N-dipropylamino, N-butylamino, N-methyl-N-ethylamino, aminomethyl, N,N-dimethylaminomethyl, N-methyl-N-ethylaminomethyl, benzyloxy and phenyloxy.

38. (New) The composition of claim 35 wherein the cyclooxygenase-2 inhibitor is selected from MK-966 (Merck & Co.); L-752,860 (Merck & Co.); L-783,003 (Merck & Co.); T-614 (Toyama); D-1367 (Chiroscience); L-748,731 (Merck & Co.); L-745,337 (Merck & Co.); 4-[5-(4-chlorophenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide; 4-[5-(4-methylphenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide; 4-[5-(3-fluoro-4-methoxyphenyl)-3-(difluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide; 3-[1-[4-(methylsulfonyl)phenyl]-4-trifluoromethyl-1H-imidazol-2-yl]pyridine; 2-methyl-5-[1-[4-(methylsulfonyl)phenyl]-4-trifluoromethyl-1H-imidazol-2-yl]pyridine; 4-[2-(5-methylpyridin-3-yl)-4-(trifluoromethyl)-1H-imidazol-1-yl]benzenesulfonamide; 4-[5-methyl-3-phenylisoxazol-4-yl]benzenesulfonamide; 4-[5-hydroxymethyl-3-phenylisoxazol-4-yl]benzenesulfonamide; [2-trifluoromethyl-5-(3,4-difluorophenyl)-4-oxazolyl]benzenesulfonamide; 4-[2-methyl-4-phenyl-5-oxazolyl]benzenesulfonamide; and 4-[5-(3-fluoro-4-methoxyphenyl-2-trifluoromethyl)-4-oxazolyl]benzenesulfonamide.

39. (New) The composition of claim 38 wherein the cyclooxygenase-2 inhibitor is MK-966 (Merck & Co.).

REMARKS

Applicants have amended the application to properly identify the geneology of this application, as reflected in the filing receipt mailed by the U.S. Patent and Trademark Office on May 9, 2000.

New claims 13-39 have been added to claim the combination therapy invention (method and related pharmaceutical composition) described by the pending application. The new combination therapy claims are supported, *inter alia*, by the disclosure beginning in the first full paragraph on page 29 and continuing over to the top of page 30. As described, a particular aspect of the invention described in the subject application is the treatment of cardiovascular disorders by a combination therapy in

which a cyclooxygenase-2 inhibitor (COX-2 inhibitor) is used in combination with an agent selected from the group consisting of (1) a lipid lowering drug, (2) an anti-oxidant, (3) a IIbIIIa antagonist, (4) an aldosterone inhibitor, (5) an AII antagonist, (6) a β-blocker, (7) asprin, (8) a loop diuretic and (9) an ace inhibitor.

Based on this disclosure, claims are specifically directed to methods and compositions wherein the COX-2 inhibitor, or its pharmaceutically acceptable salt, is used in combination with a lipid lowering drug, such as (1) an IBAT inhibitor, (2) a fibrate, (3) niacin, (4) a statin, (5) a CETP inhibitor and (6) a bile acid sequestrant. Use of the COX-2 inhibitor and a statin is specifically claimed.

Claims also recite specific classes of COX-2 inhibitors based, *inter alia,* (1) on the description found in the paragraph bridging pages 4 and 5, (2) on the description found in the paragraph bridging pages 7 and 8 and (3) on the description in the paragraph bridging pages 15 and 16.

The claims also are fully supported by the original provisional application Serial No. 60/044,626, the benefit of which is claimed in the subject application. In particular, a comparison of the subject application and the cited provisional application shows that the description of each is identical. As a result, for the very same reasons advanced above for the pending application, the claims are fully supported by the provisional application.

This Amendment is accompanied by an Information Disclosure Statement and prompt consideration of that Statement also is requested. One document listed in the Statement deserves specific reference. U.S. 6,245,797, *inter alia*, which issued on June 12, 2001, claims a method for reducing the risk of developing atherosclerotic disease by using a combination of an HMG-CoA reductase inhibitor and a COX-2 inhibitor. It is our understanding that HMG-CoA reductase inhibitors are also know as statins. By virtue of the April 18, 1997 filing date of the provisional application, however, the '797 patent is not citable against the subject application as prior art under §§102 and 103 of the Patent Statute.

RESTRICTION/ELECTION

The Office Action requires restriction under 35 USC 121 and 372 between a Group I invention drawn to a method of preventing an inflammation related cardiovascular disorder with the recited compounds (including compounds of formula I) and a Group II invention also directed to a method of preventing an inflammation related cardiovascular disorder but with a compound embraced by formula II (as presented in claim 10 and on page 16). The Office Action contends that claims 1-2 and 5-12 are generic.

Because these inventions are related as genus (Group I) and partially overlapping sub-genus (Group II) and thus are not unrelated, applicants traverse the requirement for restriction. Nonetheless, in response to the restriction requirement, applicants elect the invention of Group I for initial prosecution.

The Office Action also requires an election of species. The Office Action presents a confusing list of the purported species as follows:

(A) Cardiovascular disorders of claims 2, 3, 4, 9 and 12;

(B) Compounds of claims 5 and 8;

(C) A substituent[s] of compound I of claims 5, 6, 7 and

(D) R4 substituents of compound II of claims 10 and 11.

The Office Action further contains the requirement that applicants "elect a single species of each to which the claims shall be restricted if no generic claim is finally held to be allowable." Applicants traverse this restriction to the extent it imposes a requirement on applicants to present amended subject matter drafted in a manner which could be asserted lacks compliance with the written description requirement of 35 USC 112, first paragraph.

In response to the election of species requirement (as understood by applicants' undersigned representative) applicants hereby elect (A) atherosclerosis as the cardiovascular disorder; (B) the compound of **4-[5-(4-methylphenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide** (of claim 5 and 8); (C) the unsaturated heterocyclyl of claim 5, the 5- or 6-member unsaturated heterocyclyl of claim 6 and the pyrazolyl of claim 7 and (D) the haloalkyl of claim 10 and the lower

haloalkyl of claim 11. Applicants believe that claims 1-3 and 5-12 read on (are generic to) the elected species. With respect to new claims 13-39, applicants believe that claims 13-22; 24-30 and 32-38 would also read on combination therapy employing the elected species.

Consequently, based on the above, prompt reconsideration and full allowance of the claims pending in the subject application are respectfully requested.

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